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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281
21125 7590 10/30/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
NOTIFICATION DATE		DELIVERY MODE		
10/30/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/828,838

Applicant(s)

KLADAKIS ET AL.

Examiner

Cherie M. Woodward

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 29-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/12/2009 and 8/12/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2009 has been entered.

Formal Matters

2. Claims 1-8, 10-14, 16-27, and 29-33 are pending. Claims 9, 15, 22, 28, and 34 have been cancelled by Applicant. Claims 29-31 remain withdrawn as being drawn to non-elected inventions. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 are under examination.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 8/12/2009 have been considered by the examiner to the extent possible. Some references have been lined through because they fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In the foreign references where only the abstract is in English, only the English language abstract has been considered. Foreign patent documents not in English have been lined through. No translations have been provided. Signed copies of the IDS statements are attached. Applicant is strongly advised to include all required information in an IDS form.

Response to Arguments

Claim Rejections Withdrawn

4. The provisional rejection of claims 1-8, 10-14, 16-27, and 32-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of copending Application No. 11/427,477, is withdrawn in light of the fact that the composition claims of the '477 application are non-elected and withdrawn. Should claims 1-14, 17-29 and 32 of the '477 application be examined, the provisional ODP rejection may be reinstated.

Claim Rejections Maintained
Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. U.S. Patent Publication US 20020127265 (12 September 2002) and Huckle et al., WO 01/85226 (published 15 November 2001), as exemplified by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), for the reasons of record and the reasons set forth herein.

Applicant argues that the examiner is incorrect in interpreting the open language of claims 1 and 19, as discussed in the Advisory Action (Remarks, p. 2). Applicant argues that the nonwoven polymeric material itself must have a density in the claimed range (Remarks, p. 2). Applicant argues that the cited prior art references either alone or in combination do not teach a nonwoven polymeric material comprising the claimed density range (Remarks, p. 2). Applicant disagrees with the examiner's recitation that "density limitations within the claimed range of 120 mg/cc...are taught by [Huckle] at page 21, line 34" (Remarks, p. 2). Applicant argues that Bowman does not teach the claimed invention, nor do the combination of Bowman and Huckle (Remarks, p. 3).

Applicant's arguments have been fully considered, but they are not persuasive. Applicant has done nothing more than continue to advance arguments the examiner has previously found unpersuasive. Applicant has not submitted any evidence of record showing that the examiner's interpretation of the prior art is misplaced. Applicant has presented attorney argument, which the examiner has rebutted with

evidence from the prior art references themselves. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (holding that when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not).

As stated of record in the Advisory Action, mailed 7/21/2009, Applicant argues that the PCL coating that is added to the felt should not be considered in the material density calculation (Remarks, pp. 6-7). Applicant's arguments and amendment have been fully considered, but they are not persuasive. The amended limitation in claim 1 was already considered by the examiner. The claim amendment just adds duplicative verbiage. Independent claims 1 and 19, which recite that the claimed device "comprises" (i.e. open language) the generic dry laid nonwoven polymeric material, do not prohibit the dry laid polymeric material from comprising a coating in order to achieve the recited density. Applicant is also referred to the rejections of record.

As explained in detail, of record, the '226 publication teaches scaffolds having a density of 120 mg/cm³ (p. 21, line 34). Applicant has previously argued that the density of the felt is actually only 93 mg/cm³ (p. 21, lines 14-15) and that the difference in scaffold density is due to a coating (p. 21, lines 20-28). Page 21 of the '226 publication describes the process of making the nonwoven scaffold. The process begins with a nonwoven felt that has a density of 60 mg/cm, which is plate pressed at high heat with spaces to produce a particular thickness and a density of 93 mg/cm³. The felt is further processed by soaking it in polycaprolactone ("PCL"), a well-known polymer. The entire process of making the scaffold results in a final product with a density of 120 mg/cm³. Applicant's argument that the examiner should not consider the PCL in considering the claim limitations, which require that the scaffold include (read as "comprising") a nonwoven polymeric material, the nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc" (compare instant claim 33). Applicant argues that the examiner should focus on the density of the material taught on page 21 of the '226 publication at an intermediate point in its production, rather than in its final form. Applicant's argument cannot be accepted in light of the claims, as written, and the teachings of the instant specification.

The instant claims specifically recite that the scaffold comprises a nonwoven polymeric material with a density in the recited range. There is no limitation in the claims as to the form of the nonwoven polymeric material and the specification discloses a number of various forms, including hybrid forms for the material of interest. Further, there is no limitation in the specification or the claims prohibiting a PCL coating on the nonwoven polymeric material. In fact, the instant specification is directly contrary to the arguments of Applicant's representative in this regard.

Applicant's own specification teaches hybrid nonwoven polymeric materials and the incorporation of polycaprolactone (PCL) into these hybrids. Paragraph 48 of the specification (p. 7) recites that the nonwoven fibers can be in the form of dry laid, wet laid, or extrusion based materials, or hybrids. "The fibers or other materials from which the nonwoven can be made are typically polymers, either synthetic or naturally occurring." "In addition, wet laid nonwovens are well known to be formed from a fiber-containing slurry that is deposited on a surface...Hybrids of these nonwovens can be formed by combining one or more layers of different types of nonwovens by a variety of lamination techniques" (p. 7, paragraph 49). Absent evidence to the contrary, the examiner reads this portion of the instant specification as permitting a PCL slurry deposition or "coating" on another type of nonwoven, such as the felt taught by the '226 publication at p. 21, in the same manner as that taught in the '226 publication. The resulting "hybrid" nonwoven polymeric material is described in the instant specification at p. 7 and is taught in the '226 publication at p. 21. Moreover, paragraphs 58 (p. 9), paragraph 61 (p. 11), paragraph 65 (p. 12), and paragraph 90 (p. 20) of the instant specification all specifically recite "hybrid" nonwovens comprising polycaprolactone (PCL).

The other cited references need not teach the limitations of the claims which are taught by the combination of the other cited references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Because Applicant's own specification recites embodiments of the claimed invention that encompass hybrid nonwoven polymeric material, including hybrid nonwoven polymeric material that meets the limitations of that taught by the prior art with the required density, Applicant's arguments are not persuasive and the rejection is maintained.

Provisional Obviousness-Type Double Patenting Rejections

8. Claims 1, 7, 10-14, 19, and 24-27 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of copending Application No. 11/856,743, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 5, second paragraph).

9. Claims 1, 7, 8, 19, 24-27, 32, and 33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of copending

Application No. 11/856,741, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 5, second paragraph).

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647